

Message

From: Scott J. Burya, Ph.D. [sburya@lawbc.com]
Sent: 8/25/2021 1:25:40 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Alwood, Jim [Alwood.Jim@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Master, Barbora [Master.Barbora@epa.gov]; Lloyd, Tyler [Lloyd.Tyler@epa.gov]; 'Cheng Xiong' [cxiong@adv-polymer.com]; Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: P-21-0043

Jeff:

The P-21-0043 case was submitted on December 16, 2020 – over eight months ago – and no Health Report has been generated.

Due to the U.S. Environmental Protection Agency's (EPA) new preference to withhold all New Chemical Reports until all reports for the submission have been completed, this has significantly delayed the submitter's ability to address any concerns, specifically those associated with worker inhalation exposure. In order to address efficiently any concerns identified by EPA, we kindly request the prompt release of all the currently available reports, specifically the Engineering and Exposure Reports.

While Bergeson & Campbell, P.C. (B&C®) understands EPA's reluctance to release reports piecemeal, waiting for the completion of the Health Report, in B&C's view, is a needless burden on EPA's already overextended Health Assessors because any updates to earlier reports require updating the Health Report.

Thank you,

SCOTT J. BURYA, PH.D.
REGULATORY CHEMIST
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-266-5013 | F: 202-557-3836 | lawbc.com

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, July 23, 2021 4:27 PM
To: Scott J. Burya, Ph.D. <sburya@lawbc.com>
Cc: Master, Barbora <Master.Barbora@epa.gov>; 'Cheng Xiong' <cxiong@adv-polymer.com>; Richard E. Engler, Ph.D. <rengler@lawbc.com>; Lloyd, Tyler <Lloyd.Tyler@epa.gov>
Subject: [EXTERNAL] RE: P-XX-XX43

Scott,

I acknowledge your request, however the current policy is to only send all that documents at one time. I am still waiting on the Human Health report to be QA/QC. Based on the draft report from March pending review the proposed Consent Order terms may be for worker protection (impervious gloves and APF of 10,000) and hazard communication for skin irritation, eye irritation, respiratory sensitization, skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity and specific organ toxicity. I have to look into a Drinking water exposure limit (DWEL). Eco is no effects at saturation. However due to the endpoints of concern I need to look into water releases that may effect general population.

The APF of 10,000 is the result of the spray application during use.
470 mg/d over 2 days bases on the cancer endpoint (diglycidyl resorcinol ether (POD 4.7e-4 mg/m3)).

Since I can not send you the reports I can go over the ones I have and read them to you. Then you can send information on the inhalation exposures during use to see if the APF can be modified. I will also look into a New Chemical Exposure

Limit (NCEL) for the PMN so that if they did air monitoring at the use sites they can adjust the APF bases on the results. I don't think it is practical to write a Consent Order to have the user wear an APF of 10,000 to spray this PMN.

Until I get the Human Health report I do want to stress getting information on the spray application since that is driving the APF. In the absence of any data the Consent Order will have the APF of 10,000 when workers are likely to be exposed. Manufacturing and Processing inhalation is negligible. If there are other chemicals in the mixture that require an APF of 10,000 during spray applications then consider that as well.

I will call you next week to touch base with your Options.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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From: Scott J. Burya, Ph.D. <sburya@lawbc.com>
Sent: Friday, July 23, 2021 3:30 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Master, Barbora <Master.Barbora@epa.gov>; 'Cheng Xiong' <cxiong@adv-polymer.com>; Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: RE: P-XX-XX43

Jeff:

I apologize for the somewhat delayed response.

When possible, can you please provide (presumably via CDX) all available new chemical reports including the Engineering, Exposure, Ecotoxicity, Health and others (e.g., Fate).

Please extend the review period by 15 days.

Thank you,

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, June 9, 2021 2:11 PM
To: Scott J. Burya, Ph.D. <sburya@lawbc.com>
Cc: Master, Barbora <Master.Barbora@epa.gov>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: [EXTERNAL] RE: P-XX-XX43

Scott,

I am still waiting on the Human Health report to be QC'd and finalized. There is the potential for cancer risk to workers for dermal and inhalation. The application at the use site is where the inhalation risk to cancer. The exposure would need an APF of 10,000.

There does not seem to be any gen pop risk. I can go over the inhalation exposure with you over the phone and give you the analog used and the PODs. Ecotoxicity is no effects at saturation so there is no risk.

The engineer used a hand held spray gun Model

Respirable particulates: PDR 4.5 mg/d LADD 0.002 mg-kg/day

Total particulates: PDR 14 mg/d, LADD 0.059 mg-kg/day (Cancer inhalation Fold factor of 2,200 with a target risk to get to 1.0e-4)

Inhalation is only expected at the Use sites cause of the application method.

The proposed Consent Order terms may be for Worker Protection (impervious gloves/clothing and NIOSH respirator with and APF of 10,000), Hazard Communication for skin irritation, eye irritation, respiratory sensitization, skin sensitization, Germ cell mutagenicity, reproductive toxicity, Specific target organ toxicity and no consumer use.

I left you a voice message also. Feel free to follow up with me for more detailed information.

Thanks

Jeff

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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From: Scott J. Burya, Ph.D. <sburya@lawbc.com>

Sent: Wednesday, June 09, 2021 12:19 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Subject: P-XX-XX43

Jeff:

I am writing to check on the status of the P-XX-XX43 case (TS number 789RTZ).

Please provide the status when possible.

Thank you,

SCOTT J. BURYA, PH.D.

REGULATORY CHEMIST

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